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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/601,971	08/09/2000	Thomas William Rademacher	1012-100US	5898

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EXAMINER
DECLOUX, AMY M

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 12/18/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/601,971	Rademacher et al.
Examiner	**Art Unit**
D Cloux, Amy	1644

-- The MAILING DATE of this communication appears on th cov r sh t with the correspond nc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Aug 9, 2000*

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-23* is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-23* are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot Program. If you have any questions or suggestions, please contact Paula Hutzell, Supervisory Patent Examiner at paula.hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

1. Applicant's submission of the instant application as a 371 is acknowledged, however Claim 1 does not provide a technical feature that is distinguished over the prior art, as evidenced by Rademacher et al. (Nature (1994), Volume 27, pages 327-341) who teach a pharmaceutical composition of antibodies against serum GPI-PLD that have been shown to block IgE-stimulated histamine release in rats mast cells, which is IPG dependent, (see entire article including page 334, first paragraph). Therefore, the instant invention lacks Unity of Invention. (It is noted that the inventive entity is not identical to the authorship of said paper because there are additional authors absent in the inventive entity).

2. Restriction is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted. A restriction is required under 35 USC 121 and 372 between one of the following groups:

Group I. Claims 1a, 2, 4-6 and 15, drawn to the embodiment of a method for making a composition for the treatment of a condition mediated by the release of IPGs comprising an antagonist, wherein said antagonist is a substance which is capable of inhibiting release of the IPGs by inhibiting the enzyme GPI-PLD

and Claim 14, drawn an antagonist of an IPG

and Claims 16-17 and 20, drawn to the embodiment of a method for inhibiting release of an IPG from a mast cell, a basophil or an eosinophil comprising exposing said cell to an IPG antagonist, in vitro, wherein said antagonist comprises an inhibitor of the enzyme GPI-PLD,

Group II. Claims 1b, 2, 3 and 15, drawn to the embodiment of a method for making a composition for the treatment of a condition mediated by the release of IPGs comprising an antagonist, wherein said antagonist is a substance which is capable of specifically binding to the IPGs and inhibiting the release of histamine caused by the IPGs

Group III. Claims 1c, 2, 7-9 and 15, drawn to the embodiment of a method for making a composition for the treatment of a condition mediated by the release of IPGs comprising an antagonist, wherein said antagonist is a substance which is capable of competing with IPGs released from mast cells, basophils or eosinophils but does not cause allergic stimulation of these cell types

Group IV. Claim 10, drawn to the embodiment of an IPG

Group V. Claims 11-13, drawn to the embodiment of a method of screening for antagonists of an IPG

Group VI. Claims 16-17 and 20, drawn to the embodiment of a method for inhibiting release of an IPG from a mast cell, a basophil or an eosinophil comprising exposing said cell to an IPG antagonist, in vitro, wherein said antagonist comprises an anti-IPG antibody

Group VII. Claims 16-17 and 20, drawn to the embodiment of a method for inhibiting release of an IPG from a mast cell, a basophil or an eosinophil comprising exposing said cell to an IPG antagonist, in vitro, wherein said antagonist a substance capable of inhibiting or preventing IPG release in mast cells, basophils, or eosinophils

Group VIII. Claims 16-17 and 20, drawn to the embodiment of a method for inhibiting release of an IPG from a mast cell, a basophil or an eosinophil comprising exposing said cell to an IPG antagonist, in vitro, wherein said antagonist comprises an antibody capable of inhibiting IPG release by inhibiting cleavage of the IPGs caused by the enzyme GPI-PLD

Group IX. Claims 16-17 and 20, drawn to the embodiment of a method for inhibiting release of an IPG from a mast cell, a basophil or an eosinophil comprising exposing said cell to an IPG antagonist, in vitro, wherein said antagonist comprises a competitive antagonist of the IPGs released from mast cells, eosinophils or basophils

Group X.Claims 16 and 18-23, drawn to the embodiment of a method for inhibiting release of an IPG from a mast cell, a basophil or an eosinophil comprising exposing said cell to an IPG antagonist, in vivo, wherein said antagonist comprises an anti-IPG antibody

Group XI. Claims 16 and 18-23, drawn to the embodiment of a method for inhibiting release of an IPG from a mast cell, a basophil or an eosinophil comprising exposing said cell to an IPG antagonist, in vivo, wherein said antagonist a substance capable of inhibiting or preventing IPG release in mast cells, basophils, or eosinophils

Group XII.Claims 16 and 18-23, drawn to the embodiment of a method for inhibiting release of an IPG from a mast cell, a basophil or an eosinophil comprising exposing said cell to an IPG antagonist, in vivo, wherein said antagonist comprises an inhibitor of the enzyme GPI-PLD

Group XIII.Claims 16 and 18-23, drawn to the embodiment of a method for inhibiting release of an IPG from a mast cell, a basophil or an eosinophil comprising exposing said cell to an IPG antagonist, in vivo, wherein said antagonist comprises an antibody capable of inhibiting IPG release by inhibiting cleavage of the IPGs caused by the enzyme GPI-PLD

Group XIV. Claims 16 and 18-23, drawn to the embodiment of a method for inhibiting release of an IPG from a mast cell, a basophil or an eosinophil comprising exposing said cell to an IPG antagonist, in vivo, wherein said antagonist comprises a competitive antagonist of the IPGs released from mast cells, eosinophils or basophils

Note: Each claim will be examined only to the extent of the elected invention.

3. The inventions listed as Groups I-XVI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

4. Groups I and IV are unique products, being drawn to an IPG and an antagonist of an IPG, respectively. They differ with respect to their structures and physicochemical properties and do not have the same corresponding technical feature.

5. Groups I-III, V, VII-XIV are unique methods. The endpoints of Groups I/II/III, V, VI/VII/VIII/IX/X/XI/XII/XIII/XIV are distinct. Thought the endpoints of Groups I, II and III are identical, they differ with respect to their ingredients. Though the endpoints of Groups VI-IX are drawn to in vitro methods while Groups X-XIV are drawn to in vivo methods, and therefore the process steps of each set of groups is distinct. Groups VI, VII, VIII and IX are distinct because they encompass distinct antagonists as ingredients. Groups X XI, XII, XIII and XIV are distinct because they encompass distinct antagonists as ingredients. Therefore, Groups I-III, V, VII-XIV do not have the same corresponding technical feature.

6. Groups VI and VI-XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product . In the present case, the product as claimed, the antagonist of IPG, can be used as an immunogen in a method for making monoclonal antibodies, and for use in a method of affinity purification, as well as in a method for inhibiting release of an IPG from a mast cell, a basophil or an eosinophil.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

8. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.
In order for more than one species to be examined, the appropriate additional examination fees must be paid. The species are as follows:

a **specific antagonist**, such as one recited in claim 9 since all antagonists contemplated by applicant do not belong to a recognized class of chemical compounds.

9. Applicant is required, in response to this action, to elect a specific species to which the claims shall be restricted if no generic claim is finally held to be allowable. The response must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

10. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

11. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

12. Claims 1-23 are generic.

13. The species are distinct each from the other because the encompassed products differ with respect to their physicochemical properties, and do not have the same corresponding technical feature.

14. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. a message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

17. Papers **other than elections** related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located In Crystal Mall 1. The faxing of such papers must conform with the notice published In the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.
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December 17, 2001

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